1 510(k) Summary

Table 5.1 510(k) Summary (As required by section 21 CFR 807.92(c))	
Submitter:	Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Contact Person:	Cameron Piron President Telephone: **416-673-6679** Email: cameron.piron@synaptivemedical.com Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Date Prepared:	May 24, 2014
Trade Name:	BrightMatter Planning Software
Common/Usual Name:	BrightMatter Planning Software
Classification:	21 CFR 892.2050 Product Code LLZ, Class II Picture archiving and communication system.
Product Code:	LLZ, Class II
Manufacturer:	Synaptive Medical Inc. MaRS Centre, South Tower 101 College Street, Suite 200 Toronto, ON M5G 1L7 Canada
Establishment Registration:	N/A
Primary Predicate Device:	**Manufacturer:** Meterialise NV **Trade name:** SurgiCase System **510(k) Number:** K073449 **Date Cleared:** Apr 16, 2008

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Secondary Predicate Device:	**Manufacturer:** BrainLab AG **Trade name:** iPlan Cranial **510(k) Number:** K113732 **Date Cleared:** May 7, 2012
Device Description	*BrightMatter Planning* is a treatment planning software that enables the user to view and process medical image data. The software is intended for pre-operative planning of neuro-surgical treatments based on image guided surgical systems. The planning software system provides the ability to visualize diagnostic images in 2D and 3D formats and fusion of image datasets. The software automatically segments the skull from the acquired image and generates diffusion tracts from DTI data. The user can also manually annotate regions of interest, resulting in structures which can subsequently be visualized in 3D. The end result of such processing is a set of images that can be used to develop a treatment plan for a neuronavigational procedure. The treatment plan is developed by a trained person. A trained person can use the software to segment structures, define regions of interest and establish one or more trajectories. The software, operated on a stand-alone computer workstation, is expected to be used by a Surgical Planner in an office setting, in preparation for one of several possible surgical procedures. The resulting treatment plan can be exported to a PACS for subsequent use in image guided surgery.
Intended Use	*BrightMatter Planning*'s indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion and image segmentation, where the output can be used for image guided surgery. BrightMatter Planning can be used for planning and simulation of cranial surgical procedures and reviewing of existing treatment plans. Typical users of the software are medical professionals, including but not limited to surgeons and radiologists.

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Summary of Technical Comparisons	Both the predicate device and the subject device (BrightMatter Planning Software) are software applications that import DICOM image data files, provide image processing fuctions such as image fusion and segmentation, and produce output that can be used for image guided surgery. The primary predicate device, SurgiCase System, is a software system that helps transfer of images from medical scanners (MR or CT). The subject device also supports transfer of images from scanners but is limited to detailed visualization of MR images. Both the predicate system and subject system provide the ability to reformat pre-operative images, segment and select regions from the scanned images and visualize the images in 3D without patient contact or surgical insult. Like the predicate device, the subject device also supports simulation and evaluation of surgical treatment options using pre-operative images. The end result in both systems is a surgical plan that cannot be subsequently altered by other users once the plan is exported. Hence, BrightMatter Planning is substantially equivalent to SurgiCase system from intended use and technological characteristics points of view and does not raise different questions of safety. The predicate device (iPlan) lists these trade names: iPlan Cranial, iPlan Stereotaxy, iPlan ENT, iPlan Spine, iPlan View and iPlan CMF. These predicate device modules include functionality that is not part of the subject device. The subject device is substantially equivalent to the predicate device's iPlan Cranial module. The subject device does not include the following predicate device functionality: ▪ Atlas assisted visualization. ▪ Functional planning using BOLD MRI mapping. Comparison of the subject device to the predicate iPlan Cranial module, shows that the two products are very similar in features and functions. The comparison was made using the following technical characteristics of the two products: - Load and import data - View and Adjustment of data - Registration points - Image fusion - Object creation - Advanced Object Planning - BOLD MRI mapping - Fiber tracking - Trajectory planning - Save and export of plans - 3D functionalities

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	The DTI-derived image creation and tractography results were compared with Siemens syngo MR B17 software and were demonstrated to be equivalent in performance.
Non-Clinical Testing	The following bench (software validation) testing was conducted on BrightMatter Planning Software: • Software verification and validation testing for each requirement specification. • Software verification and validation testing for each algorithmic function. • Software verification and validation testing at the unit, integration, and system level. The following quality assurance measures were applied during software development: • Software Development Life Cycle • Software Risk Assessment. • Risk Assessment of Off-the-Shelf (OTS) Software. • Software Configuration Management and Version Control. • Software issue tracking and resolution.
Design Validation	Design validation was performed using the BrightMatter Planning Software in actual and simulated use settings. The results support substantial equivalence to the predicate device and demonstrate that the BrightMatter Planning Software is safe for its intended use.
Clinical Testing	This technology is not new, therefore a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the non-clinical testing.

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Conclusion:	We conclude that the results of testing show the BrightMatter Planning Software to be substantially equivalent to the predicate devices. The BrightMatter Planning Software has the same technological characteristics as the predicate devices in that it has a similar intended use, same general operating principle, and same technology. The specific details of the predicate device may vary from those of BrightMatter Planning Software, but testing shows that similar results are produced. Performance of DTI-derived image generation and tractography results were compared with Siemens syngo MR B17 and were shown to be equivalent. It has been shown in this 510(k) submission that the differences between the BrightMatter Planning Software and the Brainlab AG iPlan Cranial (K113732) do not raise any questions regarding safety and effectiveness. The BrightMatter Planning Software, as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

Synaptive Medical, Inc.
% Mr. Cameron Piron
President
MaRS Centre, South Tower
101 College Street, Suite 200
Toronto Ontario M5G 1L7
CANADA

Re: K140337
Trade/Device Name: BrightMatter Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2014
Received: April 28, 2014

Dear Mr. Piron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140337

Device Name
BrightMatter Planning Software

Indications for Use *(Describe)*
BrightMatter Planning's indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion and image segmentation, where the output can be used for image guided surgery. BrightMatter Planning can be used for planning and simulation of cranial surgical procedures and reviewing of existing treatment plans.
Typical users of the software are medical professionals, including but not limited to surgeons and radiologists.

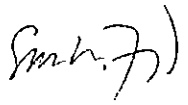
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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